UNIVERSITY OF WASHINGTON
and
CHILDREN'S HOSPITAL AND REGIONAL MEDICAL CENTER
CONSENT FORM

PRECURSORS TO DIABETES IN JAPANESE AMERICAN YOUTH

Principal Investigator:
Edward Boyko, MD, MPH, Professor, Department of Medicine,
Co-Investigators:

Graduate Research Assistants:

24 hour emergency phone numbers: Dr. at University of Washington Medical Center.
Dr. Boyko at . Dr. at Children's Hospital and Regional Medical Center

Investigator's Statement:

PURPOSE AND BENEFITS

In the past, type 2 diabetes has usually been seen in middle-aged and older adults. In recent years, we are seeing more children with type 2 diabetes. We think this is happening because children are overweight and less physically active. Most children who develop type 2 diabetes get it around the time of puberty. Some ethnic minority children, such as Native Americans, African Americans, and Hispanics, seem to be at especially high risk. Based on information from studies of school children in Japan and our studies in Japanese-American adults, we think that Japanese-American children may also be at high risk. This may happen even though they are not overweight. While the number of children with type 2 diabetes is still fairly small, most experts think the numbers are likely to increase. The purpose of this research study is to learn more about why some children develop type 2 diabetes, and to learn how changes over time (before, during, and after puberty) affects their chance of getting diabetes.

In this study we will ask you and your child to keep track of the types of foods your child eats, and a dietitian will review this record with both you and your child. Questions about the child's physical activity, medical history and family history will also be asked. These interviews will be conducted by members of our research staff. The dietitian will be available to answer any questions you may have about your child's diet and exercise habits. We will also measure your child's blood pressure, cholesterol, and blood sugar level. We do not expect this study to directly benefit your child. While we expect the test results will be normal, there is a small chance that your child could benefit if these tests detect a problem early on that can be treated by your child's regular doctor. We also hope the information learned from this research may help doctors to give better care to children in the future who have type 2 diabetes.

PROCEDURES

This study involves two visits, one now and another one in two years. Each visit includes: a) the interviews with you and your child described above, b) two different imaging tests to measure body fat, c) a physical examination, and d) blood tests, which will be done before and after an injection of a sugar water. The entire visit will take about 4 hours. We will send you a letter to arrange a second visit in two years. The second visit will be the same as the first visit. We may send you another letter to see if your child would be willing to return for additional visits in the next few years if the study is approved to continue.

One of the imaging tests is an x-ray called a DEXA scan. This test allows us to measure the amount of fat, muscle, and bone in the body using a very small amount of x-rays. It will take about 20 minutes to set up the machine and position the child, but the test itself takes about 6 – 7 minutes. The DEXA scan will be done at 1107 NE 45th Street, Suite 440, which is near the University of Washington. The other imaging test will be an MRI scan of a small area of the abdomen. The MRI uses magnets to find out how much fat, muscle, and bone there is in the body. The entire process will take about an hour including time to set up the machine properly and check the images, but the test itself will take only about 20 minutes. The MRI will be done at the University of Washington Medical Center. We will try to arrange these two tests on the same day as the rest of the evaluation, unless it is more convenient for you to do it on separate days.

The following are carried out at the Children's Hospital and Regional Medical Center. The interview includes questions about your family's educational level and income, your child's medical history, your child's family history, and questions about your child's diet and physical activity. You or your child do not have to answer a question if you don't want to. We will also ask that you keep a record of what your child eats for the 3 days before the visit. The physical examination measures height, weight, waist size, blood pressure and heart rate. We will also briefly examine your child to determine their stage of sexual development as is typically done at a routine well-child check-up. This involves a brief examination of the breasts and genitalia. A parent is welcome to remain in the exam room, in addition to the doctor and nurse, if the child so desires.

We will also take fasting blood samples. Your child will need to go without food or drink, except for water, for about 10 hours the night before the blood tests. We will place an intravenous (IV) catheter in your child's arm so that we can draw several blood samples through the IV. This way your child will only be poked one time for the blood samples that are taken. When the IV is put in, we will draw blood to test for a variety of factors related to type 2 diabetes, including blood sugar (glucose), cholesterol, and several type of hormones. We will then inject a small amount of sugar water through the IV, and then draw several blood samples every few minutes for the next 40 minutes. The total amount of blood taken will be about 4 tablespoons (2 ounces) per visit. The IV will be removed after about one hour.

We will also collect DNA from the cells in the blood. DNA is how genes are coded in the body. Genes determine how the body is put together so that the different parts of the body can work properly. We will use this DNA in future studies to test for various genes to see how the body uses glucose, how it stores fat, and other functions related to diabetes and heart disease. This information may help us to understand how diabetes develops. However, there are currently no DNA tests to diagnose heart disease or diabetes, and no conclusions can be drawn about the health of a particular person based on these DNA test results. This information will be used for research purposes only. We will not send you or your child the results of these DNA tests. If you do not want us to do tests on your child's DNA, just mark the box at the bottom of this form that says No, and we will not save a DNA sample. Your child can still take part in the study even if you decide not to have your child's DNA stored permanently.

RISKS, STRESS, OR DISCOMFORT

The amount of radiation from the DEXA scan is about 3% of the total radiation that the average person living in the United States receives from natural background radiation in the environment. There is no radiation exposure from the MRI test. Some children may feel embarrassed during the physical exam. In taking the blood samples, there may be temporary discomfort, and a bruise may form at the point where the IV catheter enters the vein. The injection of glucose can also cause temporary discomfort. Very rarely, injection of glucose can cause painful swelling around the vein. This is uncomfortable but usually goes away by itself within a few days. Sometimes, being asked questions can be stressful. You or your child may choose not to answer any question(s).

OTHER INFORMATION

We will send you a copy of your child's blood sugar and cholesterol results about 4 weeks after your visit. If the results are abnormal, we will recommend that your child be evaluated by his or her regular doctor. If you give us written permission at the time of the visit, we will also send your child's doctor a copy of these test results, as well as your child's height, weight and blood pressure.

Participation will be kept confidential, within the limits of the law. No names or other identifying information will be used in any publications or presentations which may result from this study. Only the study investigators and staff will have access to identifying information such as name or medical record number. We plan to keep this

information for 15 years after the last visit. DNA samples will be kept in our laboratory and only the investigators listed on this form, or those who have been given approval by these investigators, will have access to the DNA. DNA samples are identified by code, and the key linking the sample code to an individual participant is kept in a secure location accessible only to the investigators.

Your child's participation is voluntary. You or your child may choose not to participate and may withdraw from the study at any time, without penalty or loss of benefits to which you or your child are otherwise entitled.

As a thank you for your child's time, we will offer them their choice of a $25 gift certificate when they complete each visit. Examples of the gift certificates include video rental, movie theaters, toy stores, activities (roller skating, miniature golf), and sporting event tickets. Also, a parking voucher will be provided if you need it.

In the event of a physical injury as a direct result of participating in this study, medical care will be available to your child at Children's Hospital and Regional Medical Center. The University of Washington will pay for medical care of physical injuries directly caused by study procedures. Please contact us at the numbers listed on the first page of this form if your child has a problem that is directly related to this study.

For questions about your/your child's rights as a research participant, contact the hospital's Institutional Review Board (IRB) at (206) 526-2023. The IRB is a committee who reviews the research to be sure that your/your child's rights as a research subject are protected.

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Signature of Investigator Date

Parents' Statement:

The study described above has been explained to me, and I voluntarily consent to have my child participate in this research. I have had the opportunity to ask questions and understand that future questions I have about the research will be answered by the investigators listed above.

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Signature of Parent/Legal Guardian Date

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Signature of Parent/Legal Guardian Date

No, I do not want my child's DNA to be stored for future research purposes.

Yes, I agree to have my child's DNA stored for future research purposes.

Copies to: Parents
Investigator's file